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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,834	02/13/2002	Johannes Booij	246152015300	5546

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EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/937,834	Applicant(s) BOOIJ ET AL.	
	Examiner Mark L. Berch	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,12-14,16-20,27-29,31,34-37,39-44,47-51,54-57 and 61-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10,12-14,16-20,27-29,31,34-36 and 63-66 is/are allowed.
- 6) ☒ Claim(s) 37,39-44,47-51,61,62 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/16/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61-62 are rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention.

Specifically:

Paragraph 2: It is unclear what this control of average particle size and density consists of.

Claim 10 does not require any particular average particle size or density, so one cannot look to the claim 10 to determine what claim 61 involves. Does this mean raising or lowering the density? Does it mean affecting the variability of the density (in cases where the product is not of uniform density, as often occurs)? The same is true of particle size.

Paragraph 1: How is this to be done? Page 9, lines 24-27 refers to doing this, but does not say specifically how. It must be noted that average particle size, so far as the examiner can find, was never actually measured or reported. As for the number of nozzles, this issue doesn't seemed to be addressed in the examples. So far as can be determined, there was

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only one nozzle used, since there is never any reference to nozzles in the plural in the actual examples. The same is true of the "the type and amount of solvents" – all the examples within the claims used just water and acetone, so there is no guidance as to how the type (and amounts) affect the average particle size.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37, 40-42, 44, 47-51, and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 4454069, 6417352, 5288861, US 20030022882 A1, 5985625, or WO 98/21212.

In 4454069, see column 5, lines 36-39, which refers to Potassium clavulanate in the form of "microcrystals ... well-defined needles or waisted plates." The latter form would avoid the provisos of the claim. The reference states that the product of this invention is "produced in pure form in large crystals which may be well-defined needles or waisted plates (i.e. butterfly-shaped)". Those plates are thus presumed to be the result of examples 3 or 4. 6417352 gives another crystallization. The form is not stated, but conditions which would be expected to obtain the rosettes were not used. In US 20030022882 A1, in example 4 and in 5985625, example 3, see the product formed in isopropanol. Applicants argue that needles would be expected, but give no reasoning, and the examiner notes that the method language in the claim is so broad as to embrace

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procedures that would produce needles anyway. In 5288861, a description of different forms ("rod-like" and "plate-like crystals") appears at column 1, lines 41-45. In WO 98/21212, see example 6.

With regard to 6417352, it is correct that the reference is silent on the matter of its e.g. density characteristic, and 4454069 is silent on the particle size characteristic. However, if mere silence were enough, then every anticipation could be overcome by simply putting in some limitation that the reference happened to be silent about, even if the material were exactly the same as the prior art. One could put in a limitation about density, color, melting point, solubility in some obscure solvent, spectroscopic data, and then simply point to the silence of the reference, as applicants have done here. Applicants could insert the limitation "which does not explode upon tapping" and point out the reference says nothing about this limitation at all.

MPEP 2112 states: "A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC"

The section goes on as follows:

"Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims."

Here, the "function is not explicitly disclosed by the reference" is the compressibility, etc. Applicants need to show that such is not actually present in the reference.

Applicants have added product-by-process limitation to claim 67 (but removed it from claim 37), which limitation these references do not meet. In product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). See also *In re Hirao*, 190 USPQ 15 (footnote 3); *Ex parte Edwards*, 231 USPQ 981; *In re Pilkington*, 162 USPQ 145, 147; *In re Dilnot*, 133 USPQ 289. Thus, a rejection is proper over a prior art reference which shows the same product, even if made by a different process.

Claims 37, 39-44, 47-51, 67 are rejected under 35 U.S.C. 102(b) as being anticipated by WO97/33564.

In WO97/33564, see the agglomerate at page 10, lines 13-23, and examples 7-11. Other particle size distributions appear at page 5-6. Potassium clavulanate in crystalline form may be presumed, since it is generally available in that form. Page 10 says, "Mixtures of agglomerates of a p-lactam antibiotic such as amoxicillin trihydrate with a second pharmaceutically active agent, e.g. potassium clavulanate...." Examples 7-11 all have Potassium clavulanate in the agglomerate.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37, 42-44, 47-51, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Box.

See example 4. The Na salt was prepared, and the solution evaporated. This material was recrystallized from water-acetone. Since clavulanates are water soluble, but insoluble in acetone, water is the solvent, and acetone the antisolvent. The sole difference is that applicants do this on the K salt, whereas the example has the Na. However, the reference makes it clear that this procedure can be used on the K salt as well; see e.g. claim 3.

The traverse is unpersuasive. It appears that an impasse has been reached. Applicants need to show that the numerous prior art compounds do not meet the limitations of the claims as presently written.

For example, applicants state of the prior art, "individual needles will always be present and visible upon microscopic examination." However, a) applicants have not demonstrated that this is true for all of the prior art references. Applicants do refer to an "exhibit 1" but there is no specific explanation of what this material is, and since there are only two pictures, this cannot possibly stand for all the prior art references that are cited and b) the claims permit up to 10% needles as well. This argument cannot avail without applicants actually showing that the prior art compounds do not meet the 0-10% needle requirement.

The same is true for the other argument about the "low bulk density" of the prior art compounds. First, note that claim 37 does not actually have a requirement to avoid low bulk density. The requirement is one of compressibility, which is a measure of the difference between tapped and loose bulk densities, expressed as a ratio to the tapped bulk density. Such a ratio could in principle be met by materials having a low loose bulk density, provided that the tapped bulk density was not too much higher. Thus, if the tapped bulk density was, say, 60% or 70% higher than the loose bulk density, then the conditions of compressibility will be met regardless of whether the loose bulk density is high or low. Second, while the example 8 table is noted, that presents compounds made by just a single prior art process, one which was not used in many of the cited references. For example, 4454069 prepared the potassium clavulanate from a different salt and using a different solvent. A vague wave to the claim 8 process being "similar to those described in the prior art" is not sufficient. Third, such reasoning does not apply to claim 67, which has no compressibility requirement at all.

With regard to powders, applicants state, "powders are not agglomerates." However, as the examiner as set forth previously (e.g. action of 6/24/04), "agglomerates" is a very broad term. It simply means a collection or mass. A powder is just a substance made up of an aggregation of small particles. There is no reason that a powder cannot be considered as an agglomerate.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571)272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at 571-272-0661. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.



Mark L. Berch
Primary Examiner
Art Unit 1624

March 30, 2005